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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/028,514	02/23/98	GORFIEN	5 0942.4110002

GRANT E REED  
STERNE KESSLER GOLDSTEIN & FOX  
SUITE 600  
1100 NEW YORK AVENUE N W  
WASHINGTON DC 20005-3934

HM12/1106

EXAMINER

WARE, D

ART UNIT	PAPER NUMBER
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1651

DATE MAILED:

11/06/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/028,514

Applicant(s)

Gorfren et al.

Examiner

Ware

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE —3— MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 7-21-00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-37, 73-77, 79-82, 106-112, 140, 143, 144-158 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-37, 73-77, 79-82, 106-112, 140, 143, 144-158 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) #16417
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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Claims 1-37, 73-77, 79-82, 106-112, 140 and 143-158 are presented for examination on the merits.

1. The request filed on June 23, 2000, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/028,514 is acceptable and a CPA has been established. An action on the CPA follows.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Information Disclosure Statements (IDS)s, filed July 21, 2000, have been received and the references submitted therewith have been considered as indicated on the enclosed PTO-1449 Forms. Further, if there is an additional IDS and PTO-1449 Form submitted by Applicants for which there is no copy enclosed herein that means such paper has not been properly filed with the case. Therefore, if this is the situation wherein Applicants note that such paper has not been considered then Applicants are requested to resubmit a copy of the IDS Form and IDS paper along with the references to be considered. The reason the examiner mentions this is because the two IDS papers filed are noted to be a second and third IDS for which presumably there is another IDS, however, this may be the previous IDS(s) already of record in the case and filed on August 11, 1998 and September 24, 1999. Clarification is requested. Of course in view of this matter if such IDS is considered on the next Office action then no fee or certification will be required as it will be treated as those second and third IDS(s) submitted on July 21, 2000. Applicants should confirm that no additional IDS Forms are required to be considered or

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resubmit those which have not been considered of record in the instant case in response to this Office action.

The amendment filed July 28, 2000, has been received and entered. Claims 78, 83 and 141-142 are canceled.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- D 3. Claims 157 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The method for replacing protein in a mammalian cell culture medium is not well taught in the specification. There would be a certain degree of unpredictability involved with the process of carrying out this method. In the absence of proper guidance it is uncertain that one of skill in the art would be capable of carrying out the claimed process without undue burden of experimentation since no exemplified disclosure is set forth for which to show one of skill how to go about replacing insulin or transferrin with the ionic chelators claimed herein. Although applicants have pointed out in the specification where support can be found for the newly added claim such support is not deemed to be sufficient for carrying out a method since no method steps have been actually carried out or exemplified in the specification. Clarification is requested.

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4. Claims 1-29, 79, 140, 154 and 158 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Israel, (U.S. Patent No. 5,318,898), previously cited in the Office action of December 23, 1999.

5. Claims and newly drawn to a chemically defined medium and method for culturing a suspension of cells. The claims are also discussed in the previous Office action.

Israel is previously discussed in the prior Office action.

The claims are similar to the disclosure of Israel and furthermore, this reference does teach suspension culturing of cells in a culture medium containing known ingredients (i.e. chemically defined culture medium). Therefore, the claims are considered to be anticipated by the cited disclosure. The claim limitations which are silent in Israel are inherent to the teachings of the cited reference. However, in the alternative that there is some unidentified characteristics for which provides for some difference between that which is claimed and the teachings of Israel then such difference is considered to be so slight as to render the claimed invention obvious. It is further important to note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' claimed method(s) differ(s) and, if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

6. Claims 30-37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Israel, discussed above, in view of World Patent 92/05246, both cited of record in the instant case.



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Applicants' arguments filed July 28, 2000, have been fully considered but they are not persuasive. In response to Applicants' argument that a chemically defined culture medium is not disclosed by Israel which is not deemed persuasive because the limitation is inherent to the teachings of Israel, it is also noted that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Furthermore, the combination was based upon the usefulness of similar media types for other cell types other than Chinese Hamster Ovary (CHO) cells. The rejection was not based upon the addition of yeast hydrolysate which Applicants allege is a component of the cited World Patent. Therefore, this rejection is maintained.

7. Claims 73-77 and 79-82 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Israel in view of the World Patent, both discussed above, and Inlow et al. also cited of record.

Applicants' arguments filed July 28, 2000, have been fully considered but they are not persuasive since Israel does indeed teach a chemically defined cell culture medium and cultivating a mammalian cell in suspension in vitro, as discussed above. Further, Inlow et al. clearly teach a serum free culture media useful for culturing viral components as claimed herein. It is clear or at least suggested in order for a culture medium to be serum free its components must be known and such media would suggest a chemically defined culture medium. Also insect cells are considered to be animal cells and one of skill would have expected successful

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results cultivating in vitro cells of both mammalian and insectal origin on similar culture medium. Therefore, Applicants' arguments are not deemed convincing and the rejection is maintained.

8. Claims 106, 143-149, 155 and 157 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Keen et al., previously cited of record in the Office action of December 23, 1999.

Claims and Keen et al. are discussed of record in the case.

The claims are so similar to the disclosure of Keen et al. that they are considered to be anticipated by the teachings of the cited reference. However, in the alternative that there are some unidentified characteristics for which applicants have not set forth herein (i.e. other than suspension culture and chemically defined culture medium), and such characteristics provide for some difference then the difference is considered to be so slight as to render the claims obvious over the cited reference. Note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine what these characteristics might be in order to establish some difference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

9. Claims 150-153 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Keen et al. discussed of record.

Applicant's arguments filed July 28, 2000, have been fully considered but they are not persuasive. Keen et al. is argued by Applicants as allegedly explicitly teaching the requirement

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for insulin, however, at Table 1, columns, 4-5, all lines, not insulin is disclosed in the medium A and it is thus, not explicitly taught as argued by Applicants. Furthermore, to vary concentrations of chelators is clearly within the purview of an ordinary artisan as is the use of various media types for cultivation of cells. The claims are prima facie obvious over the cited reference and the standard of obviousness has been well applied with the cited reference. This rejection is maintained.

10. Claims 106-112, 143-153 and 156-157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen et al. in view of Israel and Inlow for those reasons of record.

Applicant's arguments filed July 28, 2000, have been fully considered but they are not persuasive. The arguments that this rejection should be withdrawn because Keen et al. teaches insulin is necessary and because Inlow relates only to insect cells are not persuasive for those reasons noted above. Keen et al. do indeed teach that chelates can replace transferrin and insulin or at least suggests the replacements thereof. Thus, the combination of these prior art references would not have led one of skill away from using chelates in place of transferrin and/or insulin etc. Further, to vary media types that are well known in the art is clearly within the purview of an ordinary artisan, as noted above. Therefore, the desirability in the art to use chelates is clearly disclosed and to vary their concentrations is well within the knowledge of those of skill in this art, as discussed *supra*. This rejection, is hereby being maintained for those reasons above and for those of record.



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All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Deborah K. Ware*  
**DEBORAH K. WARE**  
**PATENT EXAMINER**

Deborah K. Ware

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October 23, 2000